INTERIM STUDY COMMITTEE ON HEALTH ISSUES

Legislative Services Agency
200 West Washington Street, Suite 301
Indianapolis, Indiana 46204-2789
Tel: (317) 232-9588 Fax: (317) 232-2554

MEETING MINUTES

Meeting Date:	June 24, 1998
Meeting Time:	10:00 A.M.
Meeting Place:	State House, 200 W. Washington St., House Chambers
Meeting City:	Indianapolis, Indiana
Meeting Number:	1

Members Present: Rep. Charlie Brown, Chairperson; Rep. Susan Crosby; Rep. Vaneta Becker; Rep. Karen Burkhardt; Rep. Phyllis Pond; Sen. Marvin Riegsecker; Sen. Beverly Gard; Sen. Robert Jackman; Sen. Glenn Howard; Sen. Vi Simpson; Sen. Cleo Washington.

Member Absent: Rep. Craig Fry.

Rep. Brown called the meeting to order at 10:15 A.M. Committee members introduced themselves. Rep. Brown briefly described the topics assigned to the Committee. [1] Staff then distributed and explained materials from the Food and Drug Administration (FDA)

[1] The charges to the Committee are contained in Legislative Council Resolution 98-2 and include the following:

"A. Study effects on consumers of changes in prescriptions of narrow therapeutic index drugs from one manufacturer of the drug to another. (HCR 22)

B. Study the use by health care providers of powdered latex gloves. (HB 1085)

C. Analyze issues relating to hospices. (SB 15)

D. Study certification & compliance standards for narcotic treatment programs. (SCR 49)

E. Study changes that have been made in the state employee health insurance program during the past 10 years, including costs to participants, covered services, claims payments and other program administrative matters. Gather comparative information concerning the state employee health program in other states.

F. Study issues related to mandatory testing of newborn infants or pregnant women for HIV. (SCR 65)".

regarding narrow therapeutic index (NTI) drugs. [2] Rep. Brown then asked Rep. Sheila Klinker to introduce the meeting's topic.

Rep. Klinker provided Committee members with a brief overview of NTI drugs and how the issue proceeded during the previous session of the Indiana General Assembly, including her introduction of HB 1218. She expressed interest in having the parties representing both sides of the issue work together to resolve the issue in favor of the safety of patients taking NTI drugs.

John Heiser, Director of Government Affairs at DuPont Merck, explained that physician notification of any interchange of NTI drugs, whether from brand to generic, generic to generic, or generic to brand, is imperative to insure optimum management of patients taking those particular drug products because drugs with the NTI label require very careful monitoring due to the narrow range between patient benefit and risk. Since so many variables impact on the performance of NTI drugs, it is important for the prescribing physician to be kept aware of any changes in the medication the patient is taking to insure proper pharmaceutical management of patients taking those drugs. Mr. Heiser indicated DuPont Merck's support of legislation mandating communication between a pharmacist and physician whenever the pharmacist intends to interchange an NTI drug upon refill. He pointed out that HB 1218 required only notification from the pharmacist to the physician, not the physician's consent. He emphasized that it is important that the physician, patient, and pharmacist all be in the loop regarding what medication the patient is taking.

Dr. Jack Hall, a cardiologist in Indianapolis, told Committee members that scientific discoveries make physicians change their own strategies on an ongoing basis. He emphasized the importance of being notified when a patient changes drugs and expressed particular concerns about mail order pharmacies. In response to questions by Rep. Brown, Dr. Hall: (1) stated that he wants to know when changes are made to the medication one of his patients is taking in order to protect the patient's health; and (2) briefly discussed the role of insurers in this decision making process and advocated a more direct role in that process for physicians.

In response to Rep. Brown's question, Bill Malloy, President of the Indiana Board of Pharmacy, explained Indiana's generic substitution law to Committee members. During this explanation, Mr. Malloy indicated that previous versions of the generic drug law required a pharmacist to receive a patient's consent before providing the patient with the generic form of a prescribed drug; however, that requirement is no longer in the statute.

Jake Hansen, who is in Government Affairs with Barr Laboratories, discussed the role of generic drugs. He indicated that generic drugs have saved consumers significant amounts of money. He suggested that DuPont Merck's support of HB 1218 is due to

---

[2] The letters from the Food and Drug Administration distributed to Committee members are on file in the Legislative Information Center, Room 230 of the State House, Indianapolis, Indiana, 46204. The telephone number of the Legislative Information Center is (317) 232-9856.

the fact that DuPont Merck wants to maintain its monopoly for Coumadin.[3]

Kathleen Jaeger testified on behalf of the National Pharmaceutical Alliance, a generic pharmaceutical industry trade association. She declared that HB 1218 is not based on either science or patient safety, but rather is an attempt by DuPont Merck to disguise an anti-competitive, anti-consumer strategy. Ms. Jaeger emphasized that studies have shown no adverse effects on patients who use generic substitutions. She briefly reviewed DuPont Merck's efforts to protect its product from competition and noted that DuPont Merck's efforts have failed on the federal level and have been largely unsuccessful in persuading other states to adopt its proposals. She asserted that Barr's product is equivalent in all respects to DuPont Merck's product, that all appropriate bodies have reviewed this topic, and that two studies support Barr's position. She concluded by stressing that there is no need for restrictions on substitutions of NTI drugs.

In response to questions from Rep. Brown, Sen. Riegsecker, Sen. Gard, Sen. Washington, Sen. Howard, and Rep. Becker, Ms. Jaeger stated the following: (1) Current state laws give physicians complete control over when to give generic drugs. The FDA has systems in place to address a problem in this area if one arises. (2) All generic drugs must meet FDA approval, and the FDA has adequate safeguards in place to determine if a generic drug meets its standards. (3) It should not be disturbing if two generic drugs for the same purpose sell for significantly different prices so long as the FDA has approved both drugs. (4) There is no need to establish a list of NTI drugs; all bodies looking at this issue during the past two years have concluded that there is no issue regarding NTI drugs. (5) Physicians are very busy professionals and shouldn't need to be disturbed in order to be informed about changes in their patients' medications. (6) Pharmacists should comply with state laws regarding generic substitutions. (7) The NTI drug substitution issue is separate from product liability laws. (8) The bottom line issue is whether DuPont Merck can protect its monopoly. (9) Two categories of generic drugs exist--those with an "A" rating may be substituted with full confidence, while those with a "B" rating should not be substituted. This information may be found in the FDA's "Orange Book". (10) She has visited more than 30 states, three of which have adopted legislation supported by DuPont Merck (Virginia, which did not adopt a list of NTI drugs, North Carolina, which adopted legislation on a different issue, and Texas).

David Certo from the Indiana Board of Pharmacy explained to Committee members that substitution of one drug for another may only be made if the products are generically equivalent. Indiana uses no particular rating system for generic drugs, but does follow FDA standards for those drugs. In response to questions from Rep. Brown and Sen. Riegsecker, Mr. Certo noted that a pharmacist and the prescribing physician would know whether a generic drug was rated AB or BB, and related that HEA 1087-

[3] A copy of materials provided by Mr. Hansen to Committee members is on file in the Legislative Information Center (see footnote 2). These materials include written copies of testimony provided by Kathleen Jaeger and Dr. Lawrence Cohen (see text for more information) as well as several articles supporting Barr Laboratory's position.

1997 provided some controls by the state over out of state pharmacies. Committee members then briefly discussed regulations on out of state pharmacies.

Dr. Lawrence Cohen from the Yale University School of Medicine described his background for Committee members. He noted that he carries on an active consultative practice in cardiology and prescribes warfarin compounds regularly. Dr. Cohen stated that, in his opinion, there is no valid scientific or public safety justification for legislation or regulations that restrict the substitution of generic warfarin sodium (Barr's product) for Coumadin (DuPont Merck's product). He suggested that imposing new legislation or regulation would increase costs and impose confusing administrative burdens on pharmacists and physicians without providing any offsetting health benefits. He emphasized that the FDA found Barr's product to be bioequivalent and therefore therapeutically equivalent to DuPont Merck's product. Dr. Cohen stressed that he believes that the two products are identical and has no hesitation in substituting one for the other. He suggested that this issue is an economic one, not based on patient safety.

In response to questions from Rep. Brown and Sen. Gard, Dr. Cohen stated the following: (1) Physicians often examine a certain base of information and yet do not always come to the same conclusions. (2) He is testifying at the expense of Barr Laboratories and is a consultant to Barr. (3) There is no question in his mind that Coumadin and warfarin sodium are absolutely identical. (4) He is not opposed to establishing a list of NTI drugs, but would be opposed to treating the drugs on such a list in a different manner than other drugs. (5) Pharmacists should not be required to inform a patient if a drug prescribed for that patient is on a special list. This information should be provided to the patient at the pharmacist's discretion.

Rep. Brown determined that Dr. Hall is not a consultant to DuPont Merck and has not had any expenses pertaining to his testifying paid for by DuPont Merck.

Dr. David Reed testified on behalf of William-Lynn-James, Inc.[4] Dr. Reed's background is in economics. He stated that the issue before the Committee is an economic one. Dr. Reed related that it costs $140,000 for each 1% reduction in penetration of generic drugs in Indiana, with benefits accruing to the manufacturers of brand name drugs. He concluded that the financial benefits of the proposed legislation accrue to a select few companies in the form of higher profits; that there are no demonstrable health benefits; that consumers, health care providers, and taxpayers bear the costs; and that only for the manufacturers of brand name NTI drugs do the benefits outweigh the costs. In response to a question from Rep. Brown, Dr. Reed stated that the issue before the Committee is not as narrow as DuPont Merck vs. Barr, but that the issue is not much wider.

Harry Webb, President of the Community Pharmacies of Indiana (CPI), testified that CPI opposes any legislation that would alter current substitution laws by creating

[4] A copy of Dr. Reed's testimony is on file at the Legislative Information Center. Please see footnote 2.

different rules for NTI drugs. [5] He focused his testimony on three points: (1) Indiana's current substitution law is very explicit and effectively provides all the safeguards necessary to protect patients. (2) Legislation for NTI drugs would create additional burdens on the Indiana Board of Pharmacy and on the Indiana General Assembly. The FDA is the appropriate body to debate these issues. (3) NTI drugs such as Coumadin are potentially harmful because of how they react in the human body, not because of difficult or different manufacturing techniques. Even when the same product is used chronically for a patient, variation in response is common. Mr. Webb noted that patients should be part of the decision process in choosing between brand name and generic drugs; however, requiring pharmacies to obtain written consent each time a substitution occurs would be extremely burdensome and would inconvenience patients. He concluded by observing that if a substitution occurs, both the name of the generic drug and the brand name must be on the label. Mr. Webb asked the Committee to make certain that any proposed regulations also apply to mail order pharmacies.

In response to questions by Rep. Brown, Rep. Pond, and Sen. Gard, Mr. Webb stated the following: (1) Each patient should be consulted as to whether the patient wants a generic drug in place of a brand name drug because patients should have choice. (2) If a patient wants a generic drug and the patient's physician indicates that the pharmacist "may substitute" for the brand name drug, the pharmacist will make the substitution. (3) He is not aware of any managed care plan that allows a pharmacist to unilaterally switch from a brand name drug to a generic drug even if the pharmacist and the prescribing physician belong to the same plan. (4) Labels on prescription bottles reflect when a generic substitution is made, but whether or not the word "generic" appears on the label depends on the computer system the pharmacy uses.

Francine Breckler, President-Elect of the Indiana Pharmacists' Alliance, told Committee members that the Alliance opposed HB 1218 for several reasons. Among these are that pharmacists are trained in drug therapies and that existing state laws provide adequate protection for patients. She noted that a proposed continuing education program for pharmacists in Kentucky regarding NTI drugs was withdrawn due to a lack of scientific basis for the program. Ms. Breckler asserted that the FDA is the correct regulatory body in this arena and that there is no need to establish a special procedure for certain drugs.

In response to questions from Sen. Simpson and Rep. Brown, Ms. Breckler noted the following: (1) For generic substitution to occur, the generic and brand name drugs must be therapeutically equivalent. (2) All drugs on a pharmacy's shelf meet FDA standards.

Committee members briefly discussed the differences between therapeutic substitutions and generic substitutions. They also discussed insurance plans that cover only particular brand name drugs.

Grant Monahan, President of the Indiana Retail Council, briefly explained why his

---

[5] A copy of Mr. Webb's testimony is on file at the Legislative Information Center. Please see footnote 2.

organization opposed HB 1218. In response to a question by Rep. Brown, Mr. Monahan declared that pharmacists working in pharmacies belonging to the Indiana Retail Council have never unilaterally substituted a generic drug for a brand name drug.

Robertine Wells, Vice President of United Senior Action, expressed concern about the price of drugs. She noted that her organization studied the NTI drug issue and concluded that no additional regulations are needed for NTI drugs. Further, she stressed that the Indiana Board of Pharmacy can regulate these drugs if needed. Ms. Wells asserted that the General Assembly shouldn't make changes based on the lobbying efforts of drug companies and should allow the current process relating to generic drugs to continue.

Jim Zieba from the Indiana State Medical Association stated that the Association had concerns about HB 1218. He stressed that it is most important to keep the current generic drug substitution statute intact. He added that the Association has no real position at this time on the NTI drug issue.

After brief discussion by Committee members, Rep. Brown announced that the Committee will discuss state employees health insurance and latex gloves at its July 8th meeting.

Rep. Brown adjourned the meeting at 12:35 P.M.